

**REMARKS/ARGUMENTS**

Applicant has carefully considered this Application in connection with the Examiner's Action, and respectfully requests reconsideration of this Application in view of the above Amendment and the following remarks.

Claims 14-19 are currently pending. Claims 1-13, 20-50, 52, and 57-60 have been withdrawn. Claims 51, 53-56 and 61 have been cancelled without prejudice.

Claim 14 is currently amended to recite a bone substitute material wherein a wall between two cells which is made of two wall ceramic material layers, and a bone substitute material having a breaking stress of more than 1 MPa. This amendment is supported in paragraphs [0026] and [0049], and throughout the specification.

**I. Claim Rejections****A. 35 U.S.C. § 102(b)/103(a)**

Claims 14, 15, 17-19, and 51 stand rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively, under 35 U.S.C. § 103(a) as obvious in view of, U.S. Patent Publication No. 2002/0165616 in the name of Heide et al. ("Heide"). The Examiner asserts that Heide teaches a bone substitute material having tubular pores and micropores that read on the claimed open cells. Applicant respectfully disagrees with the Examiner's arguments and asserts that Heide does not disclose or suggest the limitations of the claims. Claim 51 has been cancelled without prejudice.

In particular, independent Claim 14, as amended, requires a bone substitute material having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow such that a wall between two cells is made of two wall ceramic material layers, and wherein the bone substitute material has a breaking stress of more than 1 MPa.

The claim language describes a hollow strut which forms a continuous (circular) single wall. The claim specifies that each wall defining a cell has two wall material layers between the cells (a first layer on one side of the strut and a second layer on the opposite side of the strut).

This structure comprising two wall ceramic material layers does not read on the disclosure of Heide, which discloses tubular pores with micropores.

The presence of hollow walls defining the cells is a significant feature of the claimed subject matter resulting from its unique methods of fabrication. As described in the specification at Paragraph [0004], the foam material used to fabricate the material itself has an open celled structure. Thus, the foam material has an open cavity running through its center, and walls between cells comprising two wall ceramic material layers.

Heide discusses at Paragraph [0045] that the formation material “is in block form,” with the tubular pores “passing through each block.” It is the block that defines the walls of Heide’s pores, which means the walls cannot be hollow. Heide also notes at Paragraph [0050] that appropriate pore spacing determines the thickness of the walls of the pores and states that thickness should be “not more than 1500 to 4000  $\mu\text{m}$  and especially from 2000 to 3000  $\mu\text{m}$ .” This further demonstrates that Heide’s pore walls are solid portions of the block formation material that exist between the pores. Heide does not disclose or suggest hollow walls.

Because Heide’s material does not exhibit walls between cells comprising two wall ceramic material layers, and because Heide’s material is not prepared using a unique method of fabrication that utilizes open celled foam material coated on the outside and inside, it is apparent that Heide’s material cannot be assumed to possess an identical physical structure or chemical composition when compared to the claimed material. Heide’s material cannot be assumed to possess the same properties as the claimed material. For that reason, it is inappropriate to assume that Heide’s material has a breaking stress of more than 1 MPa, or that Heide’s material possesses any other properties found in the claimed subject matter.

In view of these reasons, Applicant respectfully asserts that Heide does not disclose or suggest all limitations of independent Claim 14, and consequently does not disclose or suggest all limitations of dependent Claims 15, and 17-19. Claims 14, 15, and 17-19, are patentable over Heide.

**B. 35 U.S.C. § 103(a)**

Claim 16 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Heide. The Examiner states that Heide does not disclose tubular pores having a length in one direction more than 20% greater than their length in the other perpendicular directions. However, the Examiner argues that diameter/length ratio is a result-effective variable that does not confer patentability in the absence of evidence of unexpected results. Applicant respectfully asserts that Heide does not teach or suggest all limitations of Claim 16.

Claim 16 depends from Claim 14, which requires a bone substitute material having approximately the form of a positive image of an open celled foam material, the walls defining the cells within the material being hollow such that a wall between two cells is made of two wall ceramic material layers, and wherein the bone substitute material has a breaking stress of more than 1 MPa. As already discussed above, Heide does not disclose or suggest a material with walls between two cells made of two wall ceramic material layers. The coating of open cell foam material on the inside and outside, followed by the removal of the foam material, creates these double walled structures that contain an open space between the walls as well as in the center. Heide does not teach or suggest this type of fabrication or this type of structure. For that reason, Heide does not teach or suggest the limitations of Claim 14 or its dependent Claim 16.

In view of these arguments, Applicant respectfully asserts that Claim 16 is patentable over Heide.

**C. 35 U.S.C. § 102(b)/103(a)**

Claims 14-16 are rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively, under 35 U.S.C. § 103(a) as obvious in view of, EP 254 557 ("EP '557"). Applicant respectfully asserts that EP '557 does not teach or suggest all limitations of Claims 14-16.

Claim 14 requires a bone substitute material wherein the bone substitute material has a breaking stress of more than 1 MPa. This property could not be present in the composition taught by EP '557, which teaches a composition made of entirely different materials. EP '557 does not teach a bone substitute material, and so is made from different materials (for example a mixture of magnesium oxide, alumina and silica, as opposed to calcium phosphate in the present

invention) with different properties. There is no need for the ceramic structure of EP '557 (which is designed for use in a filter) to have as high a breaking stress as that required for a bone substitute material.

In view of these arguments, Applicant respectfully asserts that Claims 14-16 are patentable over EP '557.

**D. 35 U.S.C. § 102(b)/103(a)**

Claim 51 is rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively, under 35 U.S.C. § 103(a) as obvious in view of, Zhang et al. (U.S. 2005/0158535). Claim 51 has been cancelled without prejudice, rendering the rejection moot.

**E. 35 U.S.C. § 103(a)**

Claims 14-19 are rejected under 35 U.S.C. § 103(a) as obvious over Zhang, in view of EP '557.

Claim 14 requires a bone substitute material wherein the cellular structure is orientated such that the cells generally have a length in one direction greater than a length in a perpendicular direction. As described above, this limitation is not taught or suggested in Zhang.

Claim 14 also requires a bone substitute material wherein the bone substitute material has a breaking stress of more than 1 MPa. Zhang expressly teaches a compressive strength of between 5 MPa to 10 MPa, which is inconsistent with the limitations of Claim 14, as amended.

Moreover, this property could not be present in the composition taught by EP '557, which teaches a composition made of entirely different materials. EP '557 does not teach a bone substitute material, and so is made from different materials (for example a mixture of magnesium oxide, alumina and silica, as opposed to calcium phosphate in the present invention) with different properties. There is no need for the ceramic structure of EP '557 (which is designed for use in a filter) to have as high a breaking stress as that required for a bone substitute material.

In view of these arguments, Applicant respectfully asserts that Claims 14-19 are patentable over Zhang, in view of EP '557.

**F. 35 U.S.C. § 103(a)**

Claims 14-19 are rejected under 35 U.S.C. § 103(a) as obvious over Twigg et al. (U.S. 4,810,685), in view of EP '557.

Claim 14 requires a bone substitute material wherein the cellular structure is orientated such that the cells generally have a length in one direction greater than a length in a perpendicular direction. This limitation is not taught or suggested in Twigg.

Claim 14 also requires a bone substitute material wherein the bone substitute material has a breaking stress of more than 1 MPa. This property is not disclosed in Twigg, and could not be present in the composition taught by EP '557, which teaches a composition made of entirely different materials. EP '557 does not teach a bone substitute material, and so is made from different materials (for example a mixture of magnesium oxide, alumina and silica, as opposed to calcium phosphate in the present invention) with different properties. There is no need for the ceramic structure of EP '557 (which is designed for use in a filter) to have as high a breaking stress as that required for a bone substitute material.

In view of these arguments, Applicant respectfully asserts that Claims 14-19 are patentable over Twigg, in view of EP '557.

**G. 35 U.S.C. § 102(b)/103(a)**

Claim 51 is rejected under 35 U.S.C. § 102(b) as anticipated by, or alternatively, under 35 U.S.C. § 103(a) as obvious in view of, Twigg. Claim 51 has been cancelled without prejudice, rendering the rejection moot.

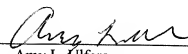
**CONCLUSION**

In view of the foregoing remarks and for various other reasons readily apparent, Applicant submits that all of the claims now present are allowable, and withdrawal of the rejection and a Notice of Allowance are courteously solicited.

If any impediment to the allowance of the claims remains after consideration of this amendment, a telephone interview with the Examiner is hereby requested by the undersigned at (214) 953-5990 so that such issues may be resolved as expeditiously as possible.

The Commissioner is hereby authorized to charge any fee or credit any refund to Deposit Account No. 10-0096.

Respectfully submitted,

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